No. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF PARALYZED VETERANS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether the Federal Circuit erred as a matter of law in interpreting the ambiguous language of 35 USC 271(e)(1) to include medical devices regulated by the Food and Drug Administration ("FDA") as well as drugs regulated by the FDA.

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Paralyzed Veterans of America submits this brief amicus curiae in support of respondent Medtronic, Inc. It is accompanied by written consents from the petitioner and the respondent.

INTEREST OF AMICUS CURIAE

Paralyzed Veterans of America ("PVA") is a non-profit organization chartered by the Congress of the United States and dedicated to serving the needs of its members—all of whom have catastrophic paralysis caused by spinal cord injuries or diseases. The Medical

and Research Affairs Department ("MARAD") of PVA funds and oversees critical spinal cord injury research—research which is critical, not only to PVA's members, but to all those with paralysis. In particular, primary funding for the Center for Neuroscience and Regeneration Research at Yale University is provided by PVA and its chapters through MARAD.

The interest of PVA in this case is to insure that vital research pertaining to the development of medical devices is not impeded by patent disputes. PVA realizes, of course, that once the research has progressed to the point of introduction of a commercial medical device, the research institution or the sponsor of the research will have to pay tribute to valid patents just the way that it will have to pay for the raw materials it uses to build the medical devices. Before the research reaches that point, however, the patent law should not be available to stifle incipient competition.

ARGUMENT

Medical research tends to be (1) expensive and (2) risky—in the sense that most medical research turns out to have been unproductive.[1] Moreover, as correctly noted by amicus Neuromedical Technologies, Inc., many developers of medical devices are small companies, and many of those small companies are

[1] There is, of course, a value to learning how *not* to accomplish a desired goal. However, that information is not, generally speaking, something that can be sold, thereby recouping the investment in the research that generated that information.

devoted to commercializing a single product.[2] During the time that such companies are engaged in their vital research work, they are uniquely susceptible to the in terrorem effect of the patent law. Since, by definition, they do not yet have a commercial product, they normally have insufficient funds to litigate patent disputes (which are notoriously expensive). Moreover, since their products have not yet been developed to the point where they have received FDA approval (and may never be developed to that point), they have little incentive to invest what funds they do have in patent litigation rather than in medical research. Thus, it is distressingly easy for a well-funded company to stifle incipient competition before the incipient competitor has gotten to the point that it can, or will wish to, fight back.

As correctly found by the Federal Circuit, "the language [of 35 USC 271(e)(1)] is fraught with ambiguity."[3] One can read it over and over again, each time convincing one's self that it means the opposite of what one convinced one's self that it meant the time before. Moreover, the legislative history is not really helpful—Congress simply didn't focus on this issue. (If it had, it might have written 35 USC 271(e) a little more clearly!)

Under the circumstances, PVA respectfully submits that what the Federal Circuit did (and what this court

[2] Brief of amicus Neuromedical Technologies, Inc. at pages 6-7. That amicus supports the petitioner, not the respondent, and it draws a different inference from this premise than does amicus PVA.

[3] *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405, 10 USPQ2d 1304, 1306 (Fed. Cir. 1989).

should do) is to read the statute so that it achieves the best result for the patent system.[4] As Chief Judge Markey of the Federal Circuit wrote of another ambiguous section of the patent statute in *Paulik* v. *Rizkalla*, 760 F.2d 170, 226 USPQ 224 (Fed. Cir. 1985) (in banc):

> A literal reading of § 102(g) is not here involved. That statute says not a word on whether suppression or concealment can or cannot be cured before the filing date of another. The court is therefore presented with a choice. Operating in the interstices of the statute, the court may read § 102(g) as permitting or forbidding such curing. Given that choice, it would seem imperative that the court choose the rule least disruptive of the daily workings of the patent system.[5]

This case could go either way as a matter of abstract logic. However, much more than abstract logic is at issue. To a significant extent, the future of research in medical devices by small companies in the United States is at issue. The Federal Circuit reached a result that favored such research—somewhat at the expense of the larger and better financed competitors of those small companies. Congress could change that result if it wants to by rewriting and clarifying 35 USC 271(e)(1). However, it is respectfully submitted that this court of generalists should not substitute its judgment for the judgment of the court of specialists below in what, at base, is a judgment call on a highly debatable point.

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[4] In this connection, it should be noted that the Federal Circuit is *the* court of patent appeals and that its members are presumed to have a special knowledge of patent law and a special sensitivity to the needs of the patent system.

[5] 760 F.2d at 1283, 226 USPQ at 233 (additional views of Chief Judge Markey). See also *A.F. Stoddard & Co.* v. *Dann*, 564 F.2d 556, 566, 195 USPQ 97, 105 (D.C. Cir. 1988) ("Courts of the Judicial Branch . . . , having the obligation to administer justice, may on rare occasions be required to delve within the interstices of a statute to do justice, not only to the individual or individuals involved, but to the statutory scheme itself.") *Stoddard* involved a longstanding ambiguity in 35 USC 116—an ambiguity which Congress later remedied by amending the statute to correspond to the court's opinion in *Stoddard*. P.L. 97-247, Sec. 6(a), 96 Stat. 320 (August 27, 1982).

Respectfully submitted,

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